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10/501,127	09/10/2004	Petrus Theodorus Johannes Willemsen	I-2002.032 US	6068

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PATENT DEPARTMENT
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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

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08/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,127

Applicant(s)

WILLEMSSEN ET AL.

Examiner

Ron Schwadron, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,12-16 and 30-42 is/are pending in the application.
- 4a) Of the above claim(s) 1,12-15,31,32,36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 16,30,33-35,38-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

1. Applicant's election with traverse of Group XII in the reply filed on 6/5/07 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because the inventions under consideration do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The putative inventions lack the same or corresponding special technical features because the claimed protein was known in the prior art (see prior art rejections in this Office Action). The amino acid sequence of said molecules is an inherent property of said proteins. Regarding the ISR, the inventions under consideration do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The putative inventions lack the same or corresponding special technical features because the claimed protein was known in the prior art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-15,17-29,31,32,36,37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/5/07.

3. Claims 16,30,33-35,38-42 are under consideration.

4. The abstract of the disclosure is objected to because it is greater than 150 words. Correction is required. See MPEP § 608.01(b).

5. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the current drawings are of such poor quality that they do not show the data that is present. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark

Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

7. Claim 39 is objected to because of the following informalities. Claim 39 refers to cancelled claim 28 wherein it should refer to claim 38. For purposes of examination it will be treated as referring to claim 38.

Appropriate correction is required.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 16,30,33,34,40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 lacks antecedent basis in claim 39 because claim 39 is a compound and claim 40 is a composition.

Claim 16 is indefinite in the recitation of "9 kD" in the absence of a recitation of the technique used to establish the molecular weight (such as SDS PAGE gel electrophoresis, etc). Different techniques have different standard errors and varying degrees of accuracy so the inclusion of the method used to establish the molecular weight is necessary to evaluate what the recited molecular weight means and encompasses.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 30,33-35,38-42 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the composition of claims 30,33,34,35,40-42. Whilst the specification discloses vaccine compositions containing the peptide of claim 16 and the various ingredients recited in the claims, there is no disclosure of the claimed compositions. A composition and a vaccine differ in scope. There is no disclosure in the specification of compositions as per recited in the claims under consideration.

There is no support in the specification as originally filed for the peptide of claims 38-40. The specification discloses the peptide of claim 16 wherein said peptide is a "9 kD Mycobacterium avium subspecies paratuberculosis protein or an immunogenic fragment thereof". Claim 38 encompasses peptides which have the stated homology with SEQ ID NO:6, but are not a "9 kD Mycobacterium avium subspecies paratuberculosis protein". There is no disclosure of such peptides in the specification as originally filed. Claim 39/40 refer to peptides comprising SEQ. ID. No. 6 wherein said peptides would encompass said molecule in association with molecules such that said molecule would not constitute a "9 kD Mycobacterium avium subspecies paratuberculosis protein".

There is no written description of the scope of the claimed inventions in the specification as originally filed (aka the claimed inventions constitute new matter).

12. The claimed inventions are not disclosed in foreign priority document EPO 02075089.9.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 16,30,33,38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Kapur et al. (US 2007/0042383).

Kapur et al. disclose the claimed protein (see SEQ. ID. No. 2498 and section [0035]) in the claimed composition (see section [0099] and [0101]). Kapur et al. disclose the claimed composition with an adjuvant wherein the media containing the peptide is a pharmaceutically acceptable carrier (see Example 13).

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 16,30,33-35,38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapur et al. (US 2007/0042383) in view of Lutticken et al. (4,788,056).

Kapur et al. disclose the claimed protein (see SEQ. ID. No. 2498 and section [0035]) in the claimed composition (except for claim 34/35) (see section [0099] and [0101]). Kapur et al. disclose the claimed composition with an adjuvant wherein the media containing the peptide is a pharmaceutically acceptable carrier (see Example 13). Kapur et al. do not teach the composition of claim 34/35. Lutticken et al. disclose

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a vaccine containing multiple antigens from multiple live stock pathogens including those recited in claim 35. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Kapur et al. disclose the claimed composition containing a 9 kD M. paratuberculosis antigen wherein M. paratuberculosis is a well known cattle pathogen (see Kapur et al., [0004]), whilst Luticken et al. disclose vaccine containing multiple antigens from multiple live stock pathogens including those recited in claim 35. One of ordinary skill in the art would have been motivated to do the aforementioned because Luticken et al. disclose a vaccine containing multiple antigens from multiple live stock pathogens including those recited in claim 35 whilst M. paratuberculosis is a well known cattle pathogen

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Ron Schwadron, Ph.D.

Primary Examiner

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RONALD B. SCHWADRON
PRIMARY EXAMINER

GROUP 1600 *1644*